Integrated pharmaceutical care

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Chapter 4

The evaluation of patient self-completion concordance forms used in community pharmacy: a comparison of two European countries

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Abstract

Objectives – To evaluate the use of patient self-completion concordance forms in Dutch and Bulgarian pharmacies. Second, to show differences in pharmacy practice and patient behaviour in two European countries: the Netherlands and Bulgaria.

Methods – A random sample of 500 pharmacies were approached per country. Patients at the start of a chronic treatment were invited to participate. At the first dispensing patients received a Self-Completion Concordance Form (SCCF). Patients were asked to fill in the SCCF at home and bring it to the appointment for their consultation at second dispensing. After the consultations patients and pharmacists were asked to fill in a questionnaire.

Key findings – Twenty-four Dutch pharmacies (99 patients) and 41 Bulgarian pharmacies (241 patients) sent back study results. A higher proportion of Bulgarian patients answered questions on the SCCF compared to Dutch patients. Patients from both countries are satisfied with the SCCF, consultation and newly started medicine.

Conclusions – Although differences between pharmacies from the Netherlands and Bulgaria exist, the SCCF can be used at the start of chronic treatment. More research in other European countries will be necessary to further develop the use of the SCCF in community pharmacies. Eventually this could be used to develop indicators to measure patient involvement in pharmaceutical care.

Introduction

Pharmaceutical care has become an important quality model for the practice of (community) pharmacy. Studies indicate that pharmaceutical care practice has been implemented in many pharmacies throughout the world improving medication use and patient outcomes[1]. Patient counseling is a crucial component in the pharmaceutical care model[2]. The consultation with patients is essential to determine what they understand about drug therapy, their expectations and their concerns. For the pharmacist this will eventually lead to a translation of patient-related needs into a problem-solving format[3]. This partnership model, concordance in medicine taking, puts healthcare providers and patients on an equal level[4]. Concordance is defined as 'an agreement reached after negotiation between a patient and a healthcare professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken' [5]. In pharmaceutical care the patient care process is the heart of the practice; in other words it is 'what occurs between the practitioner and the patient' on a daily basis in order to assess patients' needs and concerns. By operationalizing the concept of concordance the patient care process can be executed in practice with consultations that respect patients' perspectives, leading to agreed treatment decisions and improved adherence[3].

Poor adherence is a significant problem in medication use, especially at start of treatment for chronic use[6-7]. Poor adherence is not only a health problem, since the condition of the patient may not be treated as effectively as possible; it is an economic problem as well: dispensing medicines that are not consumed have high costs and ineffective therapy could lead to extra costs as well[8]. Although the importance of pharmaceutical care and patient involvement is becoming more and more acknowledged, it has not been implemented everywhere. To improve pharmaceutical care and increase patient participation a higher awareness among health professionals of the importance of pharmaceutical care is needed.

In recent years, pharmaceutical care practice has been increasingly implemented in Dutch community pharmacies. Pharmacists still mainly get paid for the filling of prescriptions but new contracts are provided for the provision of other activities like consultations and medication reviews[9]. In Bulgarian pharmacies pharmaceutical care is not implemented yet. However, changes have been made to the pharmacy education curriculum to teach pharmaceutical care practice to students. This is a first step for implementation in pharmacy practice[10].

The Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Care (CD-P-PH/PC) coordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM) (Council of Europe) was entrusted '…to improve pharmaceutical care and pharmaceutical practices in Europe through public health oriented policies and practical programmes, putting first the needs of patients and society in general, having in mind the social and ethical context of healthcare…"[11]. The Committee of Experts CD-P-PH/PC set up a working programme dealing with the assessment of the quality of pharmaceutical care and medication use in Europe and its impact on patients' quality of life in order to provide support for health policy-makers and to improve

professional standards for all professionals involved in the medication chain. The above mentioned Council of Europe project is carried out with the support of scientific collaborators. In this project there is a need to study the quality of patient involvement in pharmaceutical care. There is a need for a tool, a self-completion concordance form (SCCF)[12], to be able to measure patient involvement. The objective of this study was to explore, in the Netherlands and Bulgaria, the feasibility of asking patients to an SCCF issued by their community pharmacist. The second objective was to show any differences in pharmacies and patient behaviour in two European countries, the Netherlands and Bulgaria.

Methods

Setting

A cross-sectional study was conducted in community pharmacies in two European countries, selected for their contrasting locations and differences in pharmaceutical care practice. The Netherlands is located in the west of Europe and Bulgaria located in the east of Europe.

Participants

The study was not designed to measure or compare patient outcomes, but to describe and evaluate the process of care. Therefore a minimum sample size to achieve statistical power was not required. A random sample of 500 pharmacies per country was approached with a letter explaining the study. Pharmacists were asked to send back a reply form if they wanted to take part in the study. Participating pharmacies received all study materials including a study manual with a description of all steps. Assistance was available by phone or email for further questions. To reduce the workload for participating pharmacists study locations were asked to include 5–10 patients each. Pharmacists were instructed to ask each patient who met the inclusion criteria to take part in the study, with a maximum of 10 patients. Patients were included during 2 weeks in November 2010 based on the below mentioned inclusion and exclusion criteria. Inclusion criteria were patients who had started any new medicine meant for a long term condition, patients aged 18 years or over and patients who gave informed consent to participate. Exclusion criteria were no personal contact with the patient (i.e. patients who did not attend the pharmacy) and patients without sufficient mental capacity.

Data collection process and tools

The SCCF was used at the start of chronic treatment (Table 1). Patients included in the study received the SCCF at first dispensing of a new medicine and were asked to fill in the form at home after 1–2 weeks of use. Patients were asked to bring the completed SCCF to the pharmacy at the time of the second dispensing of their medicine, when a consultation with the pharmacist was also arranged. In the Netherlands the first dispensing always provides medication for a maximum of 14 days;

Table 1. Self-Completion Concordance Form (SCCF).

1.	**What would you like to know about this medicine (or medicines)?** Please write the first things that come to your mind.
2.	**What are your expectations of the effects of this medicine or medicines?** Please give examples of how you expect the medicine(s) to affect your normal daily activities.
3.	**Have you experienced problems using this medicine in the first weeks?** What, if any, practical problems or unwanted effects did you experience during the use of the medicine? Please write 'YES' and describe them briefly or write 'NONE'.
4.	**If you have concerns about taking this treatment for long term, what are your concerns?** For example, are you aware and concerned about any possible side effects? Are you concerned in any way about how to fit in the taking of the medicines within your normal daily routine and activities, including remembering to take them?
5.	**What would be a reason for you to stop using this medicine?** If you expect to stop using this medicine please explain when that would be and why.

therefore the consultation and second dispensing was scheduled 14 days after first dispensing. In Bulgaria medicines are dispensed for 1 month, so the consultation was combined with second dispensing after 1 month. The consultation was performed by the pharmacist and focused on patients' needs as identified by their answers on the SCCF. After the consultation patients received a further questionnaire. Once all patient consultations had been undertaken pharmacists were asked to complete a questionnaire and return it, together with all study materials (SCCFs, patient and pharmacist questionnaires), to the researchers.

The SCCF is based on results from a previous study[12], and includes items related to the most frequently reported patient needs in pharmaceutical care practice[3]. The form consists of five questions covering five subjects: knowledge, expectations, problems, concerns and reasons to stop (Table 1). The patient questionnaire contained 11 statements about the SCCF, the consultation and the newly started medicine (Table 2). Each question defined five answer categories (strongly agree, agree, not sure, disagree, strongly disagree). Patients were asked to fill in the questionnaire in the pharmacy

Table 2. Statements on patient questionnaire.

Category	Statement
Usefulness of SCCF	1. It helped me what to ask during the consultation. 2. It was *not* useful during the consultation. 3. It was useful in general. 4. It helped me to raise new questions during the consultation.
Consultation	5. It covered all the points in my checklist. 6. It gave me *no* information that was useful to me. 7. It answered to all the questions I had in mind. 8. Afterwards I still had unanswered questions. 9. I thought the consultation was useful in general.
Medicine	10. I believe this medicine was the best choice for me. 11. I feel involved in the decision to use this medicine.

and give it to the pharmacist in a sealed envelope. The pharmacist was asked to add to the SCCF details of the location of the consultation. The pharmacist questionnaire contained general questions about the pharmacy, their opinion about the SCCF and consultation, and questions about the recording of consultations in the pharmacy.
All study materials were originally developed in English. Countries translated the documents to their own language. A professional translating centre performed translation to native languages, including a translation back to English to increase reliability and validity of the translations.

Data analysis

Data were entered in a Microsoft Access data sheet and analysed using descriptive statistics from Microsoft Access, Microsoft Excel, and SPSS 18.0.3. Differences in response to the questions on the SCCF were described using confidence intervals. Statements from the patient questionnaire were grouped into three categories: general usefulness of the SCCF, the consultation, and the medicine (Table 2). Answers on questions 2 and 6 were reversed because these questions contained a negative statement where other questions contained positive statements. Average scores for the three categories were calculated per country. Differences between countries were calculated using independent samples t-test. Statistical significance was taken as $P < 0.05$.

Ethical approval and patient privacy

The Independent Ethics Committee in Leeuwarden (the Netherlands) and Sofia (Bulgaria), determined that this study posed no risk to patients. Patients could decide on participation by accepting the use of a SCCF. Data were collected and analysed anonymously. The SCCFs and questionnaires had a unique number, which allowed the possibility of linking patient questionnaires to corresponding SCCFs and pharmacy questionnaire. Study materials did not contain any information with which identification of the patient or the participating pharmacy would be possible.

Results

In the Netherlands 46 pharmacies (response rate 9.2%) agreed to participate and eventually 24 pharmacies (response rate 52.2%) sent back study results concerning a total of 99 patients. In Bulgaria 41 pharmacies (response rate 8.2%) agreed to participate and results were received from all 41 pharmacies (response rate 100%) concerning 241 patients. Data sets were not complete for three Dutch and four Bulgarian patients. For the Netherlands we analysed 96 SCCFs and patient questionnaires, and 24 pharmacist questionnaires. For Bulgaria we analysed 237 SCCFs and patient questionnaires and 41 pharmacist questionnaires. The classes of medicines used were comparable for both countries. The majority of patients received a new medicine for a cardiovascular disease (the Netherlands 60.6%, Bulgaria 51.0%) followed by medicines for alimentary tract and metabolism (the Netherlands 19.2%, Bulgaria 17.8%).

SCCF

Table 3 shows the percentages of patients who answered the questions on the SCCF. A higher proportion of Bulgarian patients answered the questions on the SCCF compared to Dutch patients. For four out of five questions this was statistically significant. However, Dutch patients had more additional questions compared to Bulgarian patients, which was also statistically significant. Blank answers to questions were distributed across all forms. Three forms (3%) were returned completely blank from the Netherlands but none from Bulgaria.

The first subject, knowledge, mainly raised questions about side effects and the effect of the medicine for Dutch patients. Twelve Dutch patients answered they had no questions. Almost half of Bulgarian patients had questions about the use of the medicine ('how many times do I have to take it daily?'), which was never mentioned by Dutch patients. Other questions by Bulgarian patients were focussed on the effect of the medicine and possible drug-drug interactions. The second subject, expectations, mainly raised questions about the effectiveness of the medicine and improved quality of life. The answers were comparable for both countries. The third subject, problems, was answered with 'none' by approximately half of the patients from both countries. Patients who answered 'yes' mainly mentioned different side effects they experienced during the first weeks of use. The fourth subject, concerns, was answered by 'no concerns' or 'no problems implementing the medicine in daily routines' by almost half of the Dutch patients. Bulgarian patients indeed mentioned many different concerns, mainly about possible side effects, ineffectiveness of the medicine and possible drug-drug interactions. Some Bulgarian patients also mentioned concerns about the influence on driving ability and the use of alcohol, which was never mentioned by Dutch patients. The final subject, reason to stop, raised similar answers in both countries. Side effects, ineffectiveness of the medicine, better alternative or when the doctor advices to stop were mentioned most. Ten Dutch patients answered they would stop using the medicine when their blood pressure, cholesterol level or sugar level was normal again. Additional questions raised mainly covered questions about side effects, drug-drug interactions and options for alternative treatment.

Table 3. Percentages of patients who answered questions on the self-completion concordance form.

Subject	The Netherlands (n=96)	Bulgaria (n=237)	95% Confidence interval difference[#]
1. Knowledge	86.5%	100.0%	3.7-20.4%*
2. Expectations	83.3%	100.0%	9.2-24.1%*
3. Problems	94.8%	98.7%	-0.7 to 8.6%
4. Concerns	88.5%	98.3%	3.2-16.3%*
5. Reason to stop	89.6%	96.6%	0.5-13.6%*
Additional questions	40.6%	19.0%	-32.6 to -10.6%*

* Statistically significant.
[#] Mean ± (1.96 x SE).

In the Netherlands the consultations mainly took place in a separate consulting room (n=62). Other answers were at the counter (n=4), at a separate desk (n=2) or during a home visit (n=2). This question was not answered for 26 consultations. In Bulgaria the consultations mainly took place at a separate desk (n=105), followed by at the counter (n=73) and in a separate consulting room (n=59).

Patient questionnaire

Table 4 shows results from the patient questionnaire. Patients from both countries were positive about the usefulness of the SCCF, the consultation and the newly started medicine; mean scores were all focussed around 1 (strongly agree) and 2 (agree). All categories showed a significant difference between the two countries; Bulgarian patients are more satisfied than Dutch patients.

At the end of the patient questionnaire there was space to write additional comments. Of the Dutch patients 17.7% wrote additional comments, mostly saying they appreciated the consultation and found it very useful and informative. Of Bulgarian patients 3.4% wrote additional questions, also to say the consultation was good and informative and they appreciated the attention given by the pharmacist. One Bulgarian comment was: 'I rely on the pharmacist because of their knowledge and advice'.

Table 4. Results for the patient questionnaire.

Subject	Country	n	Mean[§]	Std deviation	Std error Mean	P value
Checklist	The Netherlands	85	2.07	0.657	0.071	0.016*
	Bulgaria	237	1.89	0.310	0.020	
Consultation	The Netherlands	88	2.29	0.415	0.044	<0.001*
	Bulgaria	234	1.96	0.300	0.017	
Medicine	The Netherlands	90	2.19	0.756	0.080	<0.001*
	Bulgaria	237	1.57	0.524	0.034	

* Statistically significant.

[§] 1, strongly agree; 2, agree; 3, not sure; 4, disagree; 5, strongly disagree.

Pharmacist questionnaire

All participating pharmacies filled in a pharmacist questionnaire. In the Netherlands pharmacies are larger compared to Bulgaria, so each pharmacy serves a higher number of patients (Figure 1) and has a higher number of staff members (Netherlands, 8.0 full-time equivalents; Bulgaria, 3.1 full-time equivalents). Almost all Dutch pharmacies (91.7%) have a separate consultation room present whereas in Bulgaria only 26.8% of the participating pharmacies mentioned they had a separate consultation room in their pharmacy. All pharmacists in Bulgaria found the SCCF useful (one pharmacist did not answer this question). In the Netherlands 18 pharmacists (75%) found the SCCF useful; five pharmacists did not find the SCCF useful (20.8%) and one pharmacist did not answer this question (4.2%). Dutch pharmacists mainly have electronic records for the recording of consultations whereas in Bulgaria most pharmacists have paper records (Figure 2).

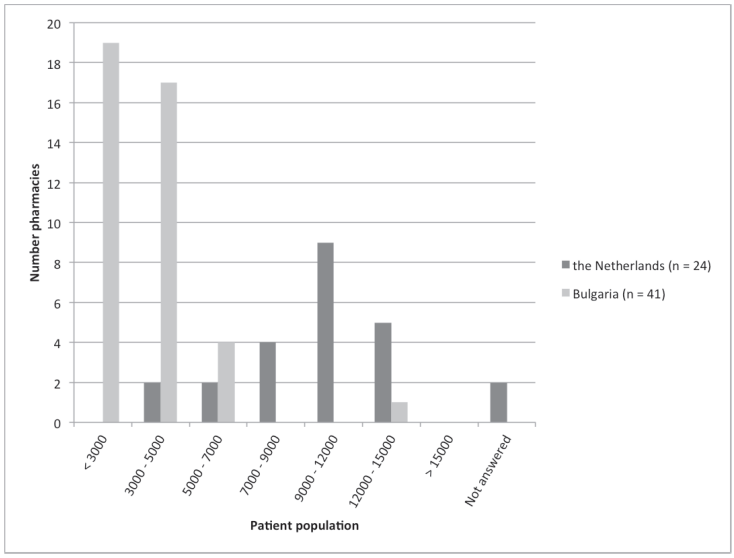

Figure 1. Average patient population per pharmacy.

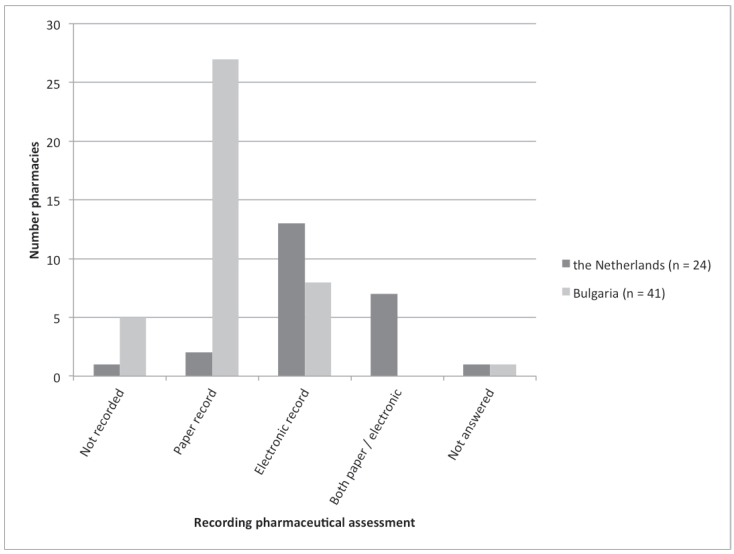

Figure 2. Recording pharmaceutical assessments.

Discussion

This study showed that the SCCF may be a useful tool for stimulating patient involvement in pharmaceutical care in Dutch and Bulgarian pharmacies, but from our findings it is unclear whether this is due to the form or the consultation. Patients had questions and concerns about their newly started medicine. Both patients and pharmacists were positive about the SCCF and the consultation, although substantial differences existed between the two countries concerning general pharmacy practice and the implementation of pharmaceutical care services. However, the differences between processes in the two different countries cause no barriers to the use of the SCCF.

Unfortunately we received a low response of pharmacists willing to participate in this study. This could create bias if only motivated and active pharmacists participated. In both countries the response rate was below 10%. A possible explanation is the high number of research projects already performed in pharmacies in the Netherlands and Bulgaria. Currently many pharmacists are asked to participate in (small) studies. Our aim was to keep the workload for pharmacists as low as possible. Therefore we asked them to include 5–10 patients per pharmacy during a recruitment period of 2 weeks. Dutch pharmacies included an average of four patients per pharmacy whereas in Bulgaria almost six patients per pharmacy were included. The study period of 2 weeks was probably too short to include 5–10 patients in one pharmacy.

Besides differences between pharmacies we also noticed a difference in patient behaviour in these two countries. Bulgarian patients answered significantly more questions on the SCCF compared to Dutch patients, whereas Dutch patients reported more additional questions. When we looked at the patient questionnaire we noticed 42.6% of Bulgarian patients still had unanswered questions after the consultation. This could mean that Bulgarian patients are less involved in their pharmacist consultations than Dutch patients. A second explanation could be a cultural difference. Patient empowerment seems more developed in the Netherlands. Our results show that Bulgarian patients are more responsive to the questions posed whereas Dutch patients are more independent, asking more of their own questions besides the five questions on the SCCF.

Another remarkable difference was noticed in the answers to the fifth question on the SCCF. Some Dutch patients answered that a reason to stop using their medicine was when their blood pressure, cholesterol level or sugar level was normal again. This is a sign that patient counselling is important to explain that the medicine in these cases is meant for chronic use. General information about the use of the medicine is given to the patient when it is dispensed. By using the SCCF communication could be more patient-centered, which will increase patients' participation and need for information, as suggested by van Hulten et al.[13].

From the pharmacist questionnaire we noticed that Dutch pharmacies mainly have an electronic or both electronic and paper documentation systems where Bulgarian pharmacies mainly use a paper documentation system. If patient consultations are performed it is important to document this to make sure information provided can be retrieved in the future. If a patient visits the pharmacy in the future with a question the pharmacy staff needs to know what has been discussed with the patient

in previous consultations. In the Netherlands more than 95% of patients always go to the same pharmacy for their prescriptions[14]. This is important to be able to record follow-up on consultations.

Implications for future research

The study was not designed to attribute cause and effect. It was a feasibility study of the use and acceptability of the SCCF. This study was the first step in a larger Council of Europe project to define and implement indicators for patient involvement in the process of pharmaceutical care. Next steps would be further detailed testing and to extend the testing to other countries.

Conclusion

Despite the substantial differences between pharmacy practice in Bulgaria and the Netherlands, pharmacists and patients in both settings found the SCCF useful at the start of a new chronic treatment. More research will be necessary to further develop the use of a SCCF and quantify its effect.

Conflict of interest

The Authors declare that they have no conflicts of interest to disclose.

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